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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,549	02/28/2002	Brigitte Chau Phan	BT12 00102703(USP3) USP8	3006
20995	7590	06/21/2005		EXAMINER
				FORMAN, BETTY J
			ART UNIT	PAPER NUMBER
				1634

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/087,549	PHAN ET AL.
Examiner	Art Unit	
BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 27 October 2004.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-15 is/are pending in the application.  
4a) Of the above claim(s) 2-6,8,15 and 1012 is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 1,7,9 and 11 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

**FINAL ACTION**

***Status of the Claims***

1. This action is in response to papers filed 27 October 2004 in which claims 1, 7, 9 and 11 were amended and in response to Information Disclosure Statement filed 4 April 2005. The amendments have been thoroughly reviewed and entered and the references listed on the 1449 have been considered as indicated on the initialed copy of the 1449.

The previous rejections in the Office Action dated 27 April 2004 under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments. New grounds for rejection, necessitated by the Information Disclosure Statement, are discussed.

The examiner for this application has changed. Please address future correspondence to Examiner BJ Forman, Art Unit: 1634.

Claims 1, 7, 9 and 11 are under prosecution.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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3. Claims 1, 7, 9 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Phan et al (U.S. Patent Application Publication No. 2003/0003464, with a priority date of 27 November 2000).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding Claim 1, 7, 9 and 11, Phan et al disclose the claimed method for identifying presence of a target. The method comprises the steps of preparing a test sample having target DNA (DYS gene), preparing reporter beads having signal DNA which is complementary to the target (¶ 166, lines 6-8), preparing capture beads having transport DNA complementary to the target DNA (¶ 166, lines 3-5) and having an anchor (capture agent, ¶ 171), blocking the beads with a blocking agent (salmon sperm, ¶ 167, lines 1-5), depositing the beads and test sample into a mixing chamber of an optical bio-disc, rotating the bio-disc allowing the beads to move into the target zone having an anchor agent for the capture agent (¶ 171-172) removing non-complexed beads and detecting dual-bead complexes to determine presence of the target DNA (Example 1, ¶ 165-176). Phan et al further anticipate a target RNA (¶ 73).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 7, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen (U.S. Patent No. 6,342,349, filed 21 July 1998).

Regarding Claim 1, 7, 9 and 11, Virtanen discloses a method for identifying presence of a target. The method comprises the steps of preparing a test sample having target DNA, preparing reporter beads having signal DNA which is complementary to the target, preparing capture DNA complementary to the target DNA (Fig. 34 A) and having an anchor (linker), blocking the beads with a blocking agent (e.g. detergent Column 38, lines 15-20), depositing the beads and test sample into a mixing chamber of an optical bio-disc, rotating the bio-disc allowing the beads to move into the target zone having an anchor agent for the capture agent removing non-complexed beads and detecting bead complexes to determine presence of the target DNA (Column 51, lines 26-Column 52, line 5). Virtanen further teaches a target RNA (Column 43, lines 59-67). The instant claims differ from the teaching of Virtanen in that while Virtanen teaches sandwich assay (Fig. 34) wherein two solid supports have target specific binding partners, Virtanen does not specifically teach both supports are beads for and detection of a dual bead complex. However, Virtanen does teach the method is especially useful for drug candidate analysis wherein solution binding is preferred in drug candidate assays (Column 57, lines 40-56) which clearly suggests dual bead binding followed by capture. Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the specific teaching of Virtanen with solution binding as the suggested (Column 57, lines 40-56) followed by dual bead detection for the expected benefit of maximizing drug candidate analysis.

***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1, 7, 9 and 11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 09/997,741. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to method for identify the presence of a target and differ only in that the instant claims are drawn to the genus method wherein the beads are generic, the isolation/capture method step is generic, the sample is generic and the target is generic. In contrast, the '711 claims define bead species (e.g. magnetic), isolation species (e.g. magnetic capture), sample species (e.g. blood, plasma, etc.) and target species (e.g. nucleic acid, protein, etc.).

The courts have stated that a genus is obvious in view of the teaching of a species see *Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the instantly claimed genus is obvious in view of the '711 species.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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8. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 4 April 2005 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### **Conclusion**

9. No claim is allowed.  
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
April 22, 2005